Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

21st November 2023

Dear [redacted]

RE: FOI 23/880

Thank you for your email on 28th October where you enquired:

"How many yellow card has been reported for diabetic ketoacidosis cases associated with SGLT2 inhibitors in County Durham and Darlington Foundation Trust?"

I can confirm that the MHRA have not received any UK spontaneous adverse drug reaction reports since the start of the Yellow Card scheme until 14/11/2023 associated with SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin, or ertugliflozin) and diabetic ketoacidosis for the following postcodes: DL3 6HX, DH1 5TW, DL14 6AD, DH3 3AT, DH8 0NB, TS21 3EE, DL12 8HT and DL13 2JR.

The accuracy of this data relies on the postcode being correctly provided by the reporter in the original Yellow Card. Additionally, the provision of postal addresses is not required to submit a report; reporters are required only to provide a contactable address which can be either an email address or postal address. If reporters only provide an email address, these will not have been included in this analysis.

When considering the spontaneous ADR data detailed above, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after use of a medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the medicine. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

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I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of this response's date and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF